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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,679	02/20/2004	Michael P. Wallace	03-573 (US01)	6996

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EXAMINER

HOLMES, REX R

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NT

Office Action Summary

Application No.

10/783,679

Applicant(s)

WALLACE ET AL.

Examiner

Rex Holmes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 4,6,9,10,12,19,21,24,25 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,7,8,11,13-18,20,22,23,26 and 28-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/03/05 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/29/04; 5/17/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

Continuation of Attachment(s) 6). Other: Other IDS reviewed 10/31/05; 6/01/06; 6/19/06.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 1-3, 5, 7-8, 11, 13-18, 20, 22-23, 26 and 28-30 in the reply filed on 9/25/06 is acknowledged. Claims 4, 6, 9-10, 12, 19, 21, 24-25 and 27 will not be examined, as they are to non-elected species.

Drawings

1. The drawings filed on 02/03/2005 are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "12" has been used to designate both the stimulating leads and brain in figure 3.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Figure 3, reference 200 (Page 11, Line 22).

3. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Figure 3, reference 200 (Page 11, Line 22). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-3, 5, 7-8, 11, 13-18, 20, 22-23, 26 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Methods of Placement of Neurostimulation Lead, Infusion Catheter, and/or Sensor via the Vasculature to the Brain (referred to hereinafter as Reference A) in further view of Boling (U.S. Pat. 6,597,953).

8. Reference A discloses treating a neurological disorder in a patient (p. 5, ll. 11-13) intravascularly delivering an electrical stimulation lead within the head of the patient (p. 3, ll. 5-6 and 17-19), and placing a stimulation lead adjacent to brain tissue (p. 3, ll. 12-14 and 17-19) cortical tissue (p. 6, ll. 1-3), the stimulation which treats the neurological disorder (p. 3, ll. 9-10); making an access point into the vasculature of the patient (p. 3, ll. 25-27; p. 8, ll. 26-27); connecting a proximal end of a stimulation lead to a stimulation source (p. 10, ll. 3-8); and chronically attaching the lead to the tissue (p. 3, ll. 21-25).

9. Reference A discloses stimulating the brain tissue with a stimulation lead to treat a neurological disorder (p. 5, ll. 11-13; p. 6, ¶2, ll. 5-7); a stimulation lead is placed in direct contact with the brain tissue (p. 4, ll. 7-9); brain tissue is deep brain tissue (p. 3, ll. 9-10); electrically connecting a stimulation lead to a stimulation source (p. 10, ll. 3-4); affixing a stimulation lead relative to the brain tissue (p. 3, ll. 30-32 & p. 10, ll. 9-10); a stimulation lead is an electrical stimulation electrode lead (p.3, ll. 23); conveying stimulation energy from a stimulation source to a stimulation lead (p. 10, ll. 5-6), wherein the brain tissue is electrically stimulated to treat a neurological disorder (p. 5, ll. 11-13).

10. Boling discloses a sensing and stimulation lead for degenerative disorders that is delivered non-vascularly through a burr hole for a more precise localization of the sensing and stimulation electrodes (Col. 1, ll. 13-16 & 55-56). The burr hole allows for the use of a cannula to allow the lead and electrode to be placed deeper into the brain than without the use of a cannula (Col. 4, ll. 30-59). Boling further discloses that that leads may be placed adjacent cortical brain tissue and may be placed chronically adjacent brain tissue (Col. 4, ll. 20-25 & Col. 12, ll. 1-3); the leads may be connected to a stimulation source or to a recording device (Col. 12, ll. 61-64).

11. Regarding claims 1-3, 5, 7-8, 11, 13-18, 20, 22-23, 26 and 28-30, Reference A discloses a method of stimulating the brain utilizing vascularly delivered electrodes that can be inserted with little to no discomfort for the patient making them less invasive to insert (p. 3, ll. 5-14). Reference A does not disclose non-vascular implantation of the leads or the combination thereof. However, Boling discloses a non-vascular implantation of stimulation leads that is more invasive but allows for more accurate placement and better readings. Boling further discloses that without the use of a cannula the electrodes cannot reach certain depths that provide accurate readings and better stimulation points (Col. 4, ll. 29-59). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the invention of Reference A to include a non-vascular implantation as taught by Boling, in order to improve the placement of the deeper implants by utilizing the non-vasculature implantation, but also to limit the number of burr holes and invasiveness of the surgery by placing the remaining leads via the vasculature.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Howard, III (U.S. Pat. 6,263,225) – Discloses a non-vascular implantation of a lead for the treatment of Parkinson's Disease, utilizing a cortical and deep brain stimulation, brain sensing and recording, and is implanted chronically.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rex Holmes whose telephone number is 571-272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Rex Holmes


George Evanisko

Primary Examiner
10/20/11